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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,507	05/08/2006	Ritsuko Ehama	053466-0446	7877

22428 7590 07/17/2008  
FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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07/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,507	<b>Applicant(s)</b> EHAMA ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment and Remarks, filed 30 Apr 2008, in which claim 1 is amended to change the scope and breadth of the claim.

This application is the national stage entry of PCT/JP04/17037, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-381470, filed 11 Nov 2003; currently an English language translation of this foreign priority document has not been filed.

Claims 1-14 are pending in the current application. Claims 5-10, 13 and 14, drawn to non-elected inventions, are withdrawn.

### ***Response to Amendment***

The amendment to the claims, in particular those claims withdrawn from consideration filed on 30 Apr 2008 does not comply with the requirements of 37 CFR 1.121(c) because amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Claims 5-10 and 13-14 are indicated as withdrawn and no explicit statement is made by Applicant regarding cancellation of claims 5-10 and 13-14, however the entire claim is not rewritten. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change

Art Unit: 1623

to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled” will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a “new” claim with a new claim number.

However, for the purpose of facilitating prosecution, the amendment to the claims, filed 30 Apr 2008, will be entered.

***Rejections Withdrawn***

Applicant's Amendment, filed 30 Apr 2008, with respect to rejection of claims 1 and 4 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter has been fully considered and is persuasive, as amended claim 1 has been amended to recite an active step for the claimed method and properly define a process and claim 4 depends from claim 1 and incorporated all limitations therein.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 30 Apr 2008, with respect to rejection of claims 1 and 4 under U.S.C. 112, second paragraph has been fully considered and is persuasive, as amended claim 1 has been amended to recite an active step for the claimed method and properly define a process and claim 4 depends from claim 1 and incorporated all limitations therein.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 30 Apr 2008, with respect to rejection of claims 1-4, 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Schwarz (US Patent 2,960,442, issued 15 Nov 1960, of record) has been fully considered and is persuasive,

Art Unit: 1623

as amended claim 1 has been amended to recite “applying said preparation to the scalp of a subject in need thereof” and Schwarz does not disclose explicitly or inherently this limitation.

This rejection has been **withdrawn**.

The following modified rejections are necessitated by Applicant's Amendment, filed 30 Apr 2008, in which claim 1 is amended to change the scope and breadth of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claim 1-4, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Tajima et al. (US Patent Application Publication US 2002/0192177, published 19 Dec 2002, of record), herein referred to as the '177 PGPub.

The '177 PGPub discloses a hair tonic, or external skin preparation, containing adenosine or adenosine 5'-phosphate as an active ingredient having hair loss preventing action and hair growth promoting action (page 1, paragraph 14-15). The '177 PGPub discloses applying said hair tonic to the scalp of a human subject (page 3, paragraph 54), anticipating instant claims 1-4. By applying said tonic to the scalp, one inherently treats hair follicle cells that are dermal papilla cells or outer root sheath cells,

Art Unit: 1623

anticipating instant claims 11 and 12. The '177 PGPub does not explicitly state that the biological pathway by which the disclosed method operates is by increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells.

Note that "increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells" is merely considered to be a new function or the unknown property or mechanism of action of a known treatment, applying said hair tonic to the scalp of a human subject. It has been settled that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above. That Applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method the '177 PGPub discloses is same as the method of the instant claims. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though applicant has proposed or claimed the mechanism (e.g., by increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells). Applicant's recitation of a new mechanism of action for the prior art method will not, by

Art Unit: 1623

itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Therefore, by practicing the process disclosed in the '177 PGPub one would inherently be practicing the instantly claimed process, anticipating instant claims 1-4, 11 and 12.

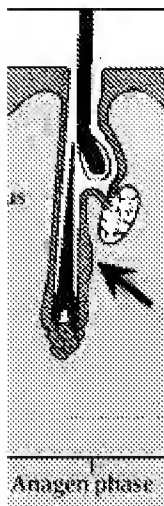
#### **Response to Applicant's Remarks:**

Applicant's Amendment and Remarks, filed 30 Apr 2008, have been fully considered and not found to be persuasive.

Applicant draws attention to the specific limitation of "maintaining and promoting hair thickening". Applicant indicates this refers to increasing the diameter of the hair according to the specification as filed, page 7, lines 1-16. However, as evidenced by the Britannica Online Encyclopedia (entry for hair, Britannica Online Encyclopedia, cited in PTO-892), hair grows in a conical shape, as indicated by the triangular cross-section:



Art Unit: 1623



. Therefore by promoting hair growth, Tajima inherently promotes hair thickening, defined as increasing the diameter of the hair, because the diameter of the conical hair increases as it grows.

Therefore this rejection is made FINAL.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended Claims 1-4, 11 and 12 are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 7,182,939, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Tajima et al., US Patent Application Publication US 2002/0192177, is the Pre-Grant Publication of Application 10/113,940, since issued as U. S. Patent No. 7,182,939. As recited above, the '177 PGPub anticipates the instantly claimed process. Claim 1 of U. S. Patent No. 7,182,939, drawn to the process disclosed in the '177 PGPub, therefore claims common subject matter to instant claims 1-4, 11 and 12.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Response to Applicant's Remarks:**

Applicant's Amendment and Remarks, filed 30 Apr 2008, have been fully considered and not found to be persuasive.

Applicant appears to refer to US Patent Application Publication US 2002/0192177 of Application No. 10/113,940, which does recite the claim:

"1. A hair tonic composition comprising..."

However, U. S. Patent No. 7,182,939, the patent issued from Application No. 10/113,940, upon which this rejection relies, recites the claim:

"The invention claimed is:

1. A method of promoting hair growth in a human comprising applying, to scalp or hair roots of said human, a composition containing, as an active ingredient, an effective amount of adenosine and a carrier therefor."

Claim 1 of U. S. Patent No. 7,182,939 is drawn to a process, the same statutory class of subject matter as the instant claims, and anticipates the instant invention as explained in the rejection above relying upon Tajima et al., US Patent Application Publication US 2002/0192177, which is the Pre-Grant Publication of Application 10/113,940, since issued as U. S. Patent No. 7,182,939.

Therefore this rejection is made FINAL.

Amended Claims 1-4, 11 and 12 are provisionally rejected on the ground of nonstatutory double patenting over claim 4 of copending Application No. 11/655,134. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 4 of copending Application No. 11/655,134 recites, "A method of preventing hair loss comprising

Art Unit: 1623

applying, to scalp or hair roots, a composition containing, as an active ingredient, adenosine and a carrier therefore.” Instant claim 4 is drawn to a method for maintaining and promoting hair thickening comprising applying to the scalp an external skin preparation containing adenosine. As recited above, applying to the scalp as recited in claim 4 of copending Application No. 11/655,134 inherently addresses the limitations of instant claims 11 and 12.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Response to Applicant's Remarks:**

Applicant's Amendment and Remarks, filed 30 Apr 2008, have been fully considered and not found to be persuasive.

As no terminal disclaimer has been filed, maintaining this rejection is deemed proper.

Therefore this rejection is made FINAL.

**Conclusion**

No claim is found to be allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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